# EXHIBIT A

# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

SMITH & NEPHEW, INC.,	)
Plaintiff,	) )
v.	) No. 02-2873 Ma/A
SYNTHES (U.S.A.) and SYNTHES- STRATEC, INC.,	) ) )
Defendants.	)

# ORDER GRANTING PLAINTIFF'S PRAYER FOR ENTRY OF A PERMANENT INJUNCTION

On November 13, 2002, Plaintiff Smith & Nephew, Inc. ("Smith & Nephew") sued Defendants Synthes (U.S.A.) and Synthes-Stratec, Inc. (collectively, "Synthes") for infringement of two patents, U.S. Patent No. 5,167,663 ("the '663 patent") and U.S. Patent No. 5,312,406 ("the '406 patent"). The patents relate to intramedullary nails and the methods used in the treatment of intertrochanteric femoral fractures using interfragmentary compression. On May 14, 2004, the court held a patent construction hearing under Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996), and entered an order construing the disputed patent terms on August 26, 2004. The case was tried discontinuously without a jury,

beginning December 6, 2004, and ending March 4, 2005. On August 26, 2005, this court issued its findings of fact and conclusions of law ("the Memorandum Opinion"). The court found that certain versions of Synthes' Trochanteric Fixation Nail ("TFN") and Proximal Femoral Nail ("PFN") infringed the '663 patent and the '406 patent.

In its complaint, Smith & Nephew prayed for relief in the form of a permanent injunction as well as damages. The court did not address the issue of a permanent injunction in its Memorandum Opinion. Both parties have had an opportunity to brief the court further on that issue, and the issue is now ready for decision. For the following reasons, Plaintiff's request for permanent injunction is GRANTED.

#### I. Background

Synthes argues principally that (i) Smith & Nephew will not be irreparably harmed because of the limited competition between the primary Smith & Nephew product covered by the '663 and '406 patents and the infringing TFN nails, (ii) Smith & Nephew has shown a willingness to be compensated fully for its patents by money damages because in the past it has licensed the patents to its competitors and has extended several licensing offers to Synthes while this case has been pending, (iii) the overall balance of hardships favors Synthes because Smith & Nephew's business will not be significantly affected by continued sales of

the infringing products, and (iv) the public health interest in having Synthes' allegedly safer and more effective TFN product available to treat femoral fractures is substantial. (Def.'s Mem. in Opp'n to Pl.'s Req. for Entry of Permanent Inj., October 3, 2005; Def.'s Resp. to Pl.'s Suppl. Br. Regarding the S. Ct.'s eBay, Inc. v. MercExchange, L.L.C. Op. at 2, May 17, 2006.)

Smith & Nephew argues that (i) irreparable harm to the sales of its patented femoral nails has been shown, together with the loss of market momentum and the ability to form customer relationships, (ii) money damages would not be adequate compensation, and (iii) the public health interest would not be adversely affected by a permanent injunction because substitute products and methods of treatment are available to the public through Plaintiff and its selected licensees. Smith & Nephew argues that it is substantially smaller than Synthes in the field of manufacturing trauma products, and, therefore, that an injunction would give Smith & Nephew the competitive support it needs to expand its customer base, increasing market competition. (Smith & Nephew's Supplemental Br. Regarding the S. Ct.'s eBay, Inc. v. MercExchange, L.L.C. Op. at 2-3, May 16, 2006; Pl.'s Second Suppl. Post-Trial Mem. Supporting Permanent Inj. (with Revised Proposed Order), October 20, 2005.)

## II. Applicable Legal Standard

A plaintiff seeking permanent injunctive relief in a patent

infringement dispute must show:

(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839, 547
U.S. (2006).

The Court in eBay held that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with the traditional principles of equity, in patent disputes no less than in other cases governed by such standards." Id. at 1841. The Court thus rejected the traditional rebuttable presumption that a permanent injunction is to be automatically awarded to the plaintiff upon a showing of the validity and infringement of the patent. Christiana Indus. v. Empire Elecs., 2006 U.S. Dist. LEXIS 54210, at \*5 (E.D. Mich. July 25, 2006). The four-factor <u>eBay</u> test is a balancing test under which the plaintiff must demonstrate that the totality of circumstances weighs in its favor. Canadian Lumber Trade Alliance et al. v. United States et al., 2006 Ct. Intl. Trade LEXIS 103, at \*11, slip op. 2006-104 (Ct. Int'l Trade July 14, 2006).

### III. Analysis

# A. Irreparable Harm Suffered by Smith & Nephew

Smith & Nephew has presented evidence that it has suffered irreparable injury to its business because of Synthes' infringement of the '663 and the '406 patents. Irreparable harm is "'often suffered when the injury can[not] be adequately atoned for in money . . . or when the district court cannot remedy [the injury] following a final determination on the merits,'" as when the plaintiff loses market share or its reputation for innovation. Wald et al. v. Mudhopper Oilfield Svcs., Inc. et al., 2006 U.S. Dist. LEXIS 51669, at \*16 (W.D. Okla. July 27, 2006) (quoting Prairie Band of Potawatomi Indians v. Pierce, 253 F.3d 1234, 1250 (10th Cir. 2001)). Although stated as two separate factors under <a href="mailto:eBay">eBay</a>, the irreparable harm requirement contemplates the inadequacy of alternate remedies available to the plaintiff. <u>Canadian Lumber</u>, 2006 Ct. Intl. Trade LEXIS 103, at \*12. Under the principles of equity to which the Court referred throughout its opinion in <a href="mailto:eBay">eBay</a>, irreparable harm means "'that unless an injunction is granted, the plaintiff will suffer harm which cannot be repaired."  $\underline{\text{Id.}}$  at \*12 (quoting <u>Studebaker Corp. v. Gittlin</u>, 360 F.2d 692, 698 (2d Cir. 1966)).

When it introduced its patented devices to the market, Smith & Nephew filled a market gap. (Trial Tr. 876:23-877:6; Trial Tr. 876:17-22 (Hall)(C).) Smith & Nephew has demonstrated flattening sale growth, starting in 2002, in the market for the infringing

devices, attributable to a decreased ability to compete in the market. (Trial Tr. 905:5-910:9.) Synthes' expert admitted that if the infringing products had not been available, he would have used Smith & Nephew products instead. (Trial Tr. 1379:4-19.)

Synthes had stagnant growth in its compression hip screw line before it started producing the infringing products because surgeons chose to treat intertrochanteric fractures with intramedullary devices instead of devices Synthes was producing at that time. (Trial Tr. 876:23-877:17 (Hall)(C); Trial Tr. 908:25-909:14 (James)(D).) Since bringing the infringing products to market, Synthes has enjoyed significant sales in both TFN and PFN products and has identified TFN as one of the two products most important to its growth. (Trial Tr. 908:15-24 (James)(D).)

Synthes admits that competition exists between Smith & Nephew's products and the infringing devices. (Def.'s Mem. in Opp. at 5.) (See also Trial Tr. 908:15-25.) Smith & Nephew has shown that direct competition exists between the infringing products and Smith & Nephew's own products. (Trial Tr. 873:11-874:15 (Hall)(C).) Synthes' TFN and PFN products have had a direct negative impact on sales of Smith & Nephew products protected by the '663 patent, as well as on other Smith & Nephew orthopaedic products. (Trial Tr. 907:24-909:14 (James)(D).) This competition has been shown to reduce Smith & Nephew's

ability to create customer relationships. (Trial Tr. 909:15-910:8.) The loss of sales due to the competition not only affects Smith & Nephew monetarily, but also inhibits the company's ability to develop new products because it interferes with the relationships Smith & Nephew is able to form with surgeons. (Trial Tr. 902:10-903:1 (James)(D); Trial Tr. 909:15-910:9 (James)(D).)

The loss of market share and the resulting lost profits and loss of brand name recognition which Smith & Nephew suffered because of Synthes' continued sale of the infringing products constitute injuries that are both incalculable and irreparable. The court finds no support for Synthes' assertions that Smith & Nephew has not been irreparably harmed because of the limited competition between the primary Smith & Nephew product covered by the '663 and the '406 patents and the infringing products made by Synthes.

Smith & Nephew has not been willing to accept royalty-type damages in lieu of the market exclusivity that it intended to secure by obtaining the '663 and the '406 patents. Even if it were, "a plaintiff's willingness to license its patent" is not "sufficient to establish that the patent holder would not suffer irreparable harm if an injunction did not issue." eBay, 126 S. Ct. at 1841 (citing the district court decision, 275 F. Supp. 2d at 712 (E.D. Virginia. 2003)).

## B. Adequacy of Remedies Available at Law

A violation of the right to exclude does not compel the conclusion that a patent holder cannot be adequately compensated by remedies at law, such as monetary damages. However, by competing in the market for the patented invention with the infringing products and by damaging Smith & Nephew's goodwill and brand name recognition, as shown above, Synthes has violated Plaintiff's exclusionary right in a manner that cannot be compensated adequately through pecuniary damages. "To recover lost profits, a patent owner must . . . show 'a reasonable probability that "but for" the infringing activity, the patentee would have made the infringer's sales, . . . a showing [that] necessarily entails a "reconstruct[ion] of the applicable market through sound economic proof." KEG Techs., Inc. et al. v. Reinhart Laimer, Sewer Equip. Corp. et al., 436 F. Supp. 2d 1364 (N.D. Ga. June 8, 2006) (quoting Ericsson, Inc. v. Harris Corp., 352 F.3d 1369, 1377 (Fed Cir. 2003)). Such a showing, speculative at best, is more challenging to make in this case because of the presence of other suppliers in this highly competitive industry and the extensive time during which Synthes has been infringing Smith & Nephew's patents. Damages due to lost sales might theoretically be proven with lesser or greater degree of certainty, but intangible losses, such as the loss of goodwill, can never be ascertained accurately.

Even if monetary damages were provable for some tangible components of Smith & Nephew's demand for damages, that relief would not necessarily be equitable. "'It is not enough that there is a remedy at law; it must be plain and adequate, or, in other words, as practical and efficient to the ends of justice and its prompt administration as the remedy in equity." Canadian Lumber, 2006 Ct. Intl. Trade LEXIS 103, at \*18 (quoting Boyce's Ex'rs v. Grundy, 28 U.S. (3 Pet.) 210, 214 (1830)). Relief in the form of monetary damages alone would not meet the ends of justice here because this remedy would allow the infringement to continue. Monetary damages generally are not an adequate remedy against future infringement because the central value of holding a patent is the right to exclude others from using the patented product. Telequip Corp. v. The Change Exchange et al., 2006 U.S. Dist. LEXIS 61469, at \*4 (N.D.N.Y., Aug. 15, 2006) (citing <a href="Honeywell Int'l Inc. v. Universal Avionics">Honeywell Int'l Inc. v. Universal Avionics</a> Sys. Corp., 397 F. Supp. 2d 537, 546 (D. Del. 2005)). Even if Synthes were to terminate its sales of the infringing products voluntarily, it would be free to return to its offending conduct, thereby further imposing monetary and intangible losses on Smith & Nephew. It is "[t]he purpose of an injunction ... to prevent future violations." Swift & Co. v. United States, 276 U.S. 311, 326 (1928). Indeed, "the entire purpose of an injunction is to take away defendant's discretion not to obey the law." Canadian

Lumber, 2006 Ct. Intl. Trade LEXIS 103, at \*19.

# C. The Balance of Hardships

Patent infringement is a continuing threat to Smith & Nephew. The hardship to Synthes of permanently enjoining its infringing conduct is limited to the injury ordinarily expected when an injunction is imposed. "Only 'hardship to the defendant [that] is not an inseparable part of the plaintiff's right' is cognizable." Canadian Lumber, 2006 Ct. Intl. Trade LEXIS 103, at \*20 (quoting Dan B. Dobbs, Law of Remedies 80 (2d ed. 1993)).

Mere hardship incurred in the process of ceasing operations, however, is not sufficient. Id. Although Synthes' effort, time and expense in redesigning the nail product used for intertrochanteric fractures might be significant, that is the consequence of a patent infringement.

No considerable hardship will be imposed on physicians or patients when the injunction is imposed because other competing products would fill any temporary void created by the injunction.

# D. The Public Interest

As a general matter, the public maintains an interest in protecting the rights of patent holders, and injunctions serve that interest. Here, a permanent injunction will further consumer access to more competitive, and thus, presumably better, products by allowing Smith & Nephew the benefit of its patents and the ability to gain greater brand recognition.

Any minor disruption to the distribution of the infringing products will not negatively affect the public or those involved in the chain of distribution because none of the data on the record establishes undisputed and enormous public reliance on Synthes' products and because other, similar products are available in the market.

#### IV. Conclusion

The balance of equities warrants injunctive relief. Smith & Nephew has demonstrated that it will suffer irreparable harm in the absence of a permanent injunction, harm that cannot be remedied adequately through the recovery of monetary damages.

Both the balance of the hardships and the impact on the public interest, although speculative, weigh in favor of Smith & Nephew. For the foregoing reasons, Plaintiff's request for permanent injunction is GRANTED.

IT IS THEREFORE ORDERED THAT Defendants, their officers, agents, servants, employees, attorneys and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise are hereby ENJOINED (i) for the life of the '663 patent, from infringing, inducing the infringement of, and contributorily infringing through the manufacturing, selling, using, offering for sale, importing, distributing or promoting in the United States (A) any version of

the Trochanteric Fixation Nail products and colorable variations thereof (except (1) fluted versions and (2) versions that have an 11 mm or a 12 mm diameter) (hereinafter, the "TFN products") and (B) any version of the Proximal Femoral Nail products and colorable variations thereof (except (1) versions that are solid and non-cannulated and (2) fluted versions) (hereinafter, the "PFN products"), as used for the treatment of intertrochanteric fractures, and from otherwise infringing or inducing others to infringe the '663 patent;

- (ii) for the life of the '406 patent, from infringing through the use, selling or offering to sell (A) any version of the TFN products and (B) any version of the PFN products, indicated for use in the treatment of intertrochanteric fractures, and from otherwise infringing or inducing others to infringe the '406 patent; and
- (iii) for the life of the '406 patent, from further publication or distribution of any product manual, sales literature, instrumentation, videos or other instructional or promotional materials distributed in the United States that describe or depict how (A) any version of the TFN products or (B) any version of the PFN products, designed, manufactured, sold or offered for sale by the Defendants, their officers, agents, employees, successors or assigns, may be used to treat intertrochanteric fractures (collectively, "instructional materials"), and are

further enjoined from communicating in any manner to any potential or actual purchaser or user of (A) any version of the TFN products or (B) any version of the PFN products that such products may be used to treat intertrochanteric fractures.

IT IS FURTHER ORDERED that Defendants, within thirty days of the issuance of this Order, sequester all instructional materials, all surgical instrumentation within Defendants' possession, title, custody or control especially designed and adapted for using (A) any version of the TFN products or (B) any version of the PFN products, in a method treating intertrochanteric fractures, and revise instructional materials to eliminate any reference to the use of (A) any version of the TFN products or (B) any version of the PFN products, for treatment of intertrochanteric fractures.

Defendants are FURTHER ORDERED to provide notice of this Order to their officers, directors, agents, servants, representatives, attorneys, employees, subsidiaries and affiliates, and those persons in active concert or participation with them, including any manufacturers, distributors, retailers, and health care providers who have been involved in the making, using, selling, offering for sale or importing of (A) any version of the TFN products or (B) any version of the PFN products, used to treat

intertrochanteric fractures, and to all other persons or entities involved in any way with the making, using, selling, offering for sale or importing of (A) any version of the TFN products or (B) any version of the PFN products, used to treat intertrochanteric fractures, and to notify all persons or entities known by Defendants to lease, own or control surgical instrumentation provided by Defendants for use in inserting into a patient TFN products or PFN products that such instrumentation may not be used to insert into a patient (A) any version of the TFN products, or (B) any version of the PFN products, to treat intertrochanteric fractures. Defendants shall take whatever means are necessary or appropriate to ensure proper compliance with this Order.

All relief not specifically granted herein is denied. This is a Final Judgment and is appealable.

So ordered this 28th day of September 2006.

s/ Samuel H. Mays, Jr.
SAMUEL H. MAYS, JR.
UNITED STATES DISTRICT JUDGE